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| APPLICATION NO.        | FILING DATE                            | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|--|-------------------------|---------------------|------------------|
| 10/001,844             | 11/16/2001                             | C. Frank Bennett        | ISPH-0617           | 2097             |
| 26259                  | 7590 09/27/2004                        |                         | EXAMINER            |                  |
| LICATLA & TYRRELL P.C. |  |                         | SCHULTZ, JAMES      |                  |
|                        | 66 E. MAIN STREET<br>MARLTON, NJ 08053 |                         | ART UNIT            | PAPER NUMBER     |
|                        |  |                         | 1635                |                  |
|                        |  | DATE MAILED: 09/27/2004 |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.   | Applicant(s)  |  |  |  |  |
|--|---|---|--|--|--|--|
|  | 10/001,844  | BENNETT ET AL.  |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit  |  |  |  |  |
|  | J. D. Schultz, Ph.D.  | 1635  |  |  |  |  |
|  | cation appears on the cover sheet with t  | he correspondence address   |  |  |  |  |
| Period for Reply   | P PERI VIO DET TO EVRIPE A MON  | THYO) EDOM  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOTHE MAILING DATE OF THIS COMMUNITY  - Extensions of time may be available under the provisions after SIX (6) MONTHS from the mailing date of this community  - If the period for reply specified above is less than thirty (30)  - If NO period for reply is specified above, the maximum state  - Failure to reply within the set or extended period for reply Any reply received by the Office later than three months at earned patent term adjustment. See 37 CFR 1.704(b).   | CATION. of 37 CFR 1.136(a). In no event, however, may a reply unication. ) days, a reply within the statutory minimum of thirty (30 uttory period will apply and will expire SIX (6) MONTHS will. by statute, cause the application to become ABAND | be timely filed  ) days will be considered timely. from the mailing date of this communication. ONED (35 U.S.C. § 133). |  |  |  |  |
| Status   |   |   |  |  |  |  |
| 1) Responsive to communication(s) file   | d on <u>14 September 2004</u> .   |   |  |  |  |  |
| , <u> </u>   |   |   |  |  |  |  |
| •  |   |   |  |  |  |  |
| Disposition of Claims  |   |   |  |  |  |  |
| 4) Claim(s) 1,5-10 and 12-15 is/are per 4a) Of the above claim(s) is/are 5) Claim(s) is/are allowed.  5) Claim(s) 1,5-10 and 12-15 is/are rejected to.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restrict are subject to part and subject to restrict are subject to part are subject to by the subject are subject to any object are subject to any object and subject are subject to any object are subject to any object and subject and subject are subject and subject and subject are subject and subject and subject and subject are subject and subject and subject and subject and subject and subject and subject are subject and subject and subject are subject and subject are subject and subject and subject are subject and subject and subject and subject are subject and subject and subject are subject and subject and subject are subject and subject are subject and subject and subject and subject are subject and subject and subject are subject and subject and subject and subject are subject and subject and subject and subject and subject are subject and subject and subject and subject and subject and | re withdrawn from consideration.  ected.  tion and/or election requirement.  e Examiner.  a) accepted or b) objected to by ction to the drawing(s) be held in abeyance.  the correction is required if the drawing(s)                               | See 37 CFR 1.85(a).<br>is objected to. See 37 CFR 1.121(d).   |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |   |  |  |  |  |
| 12) Acknowledgment is made of a claim a) All b) Some * c) None of:  1. Certified copies of the priority 2. Certified copies of the priority 3. Copies of the certified copies  | documents have been received. documents have been received in App of the priority documents have been re- nal Bureau (PCT Rule 17.2(a)).  | lication No ceived in this National Stage   |  |  |  |  |
| Attachment(s)  |   |   |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date   |   |   |  |  |  |  |
| Notice of Draftsperson's Patent Drawing Review (P3) Information Disclosure Statement(s) (PTO-1449 or Paper No(s)/Mail Date   | , a c 16)   | mal Patent Application (PTO-152)  |  |  |  |  |

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#### **DETAILED ACTION**

## Status of Application/Amendment/Claims

Applicant's response after final filed September 14, 2004 has been considered. Rejections and/or objections not reiterated from the previous office action mailed June 24, 2003 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments with respect to claims 1, 5-10, and 12-15 have been considered but are most in view of the new ground(s) of rejection set forth below.

### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, and by dependency claims 5-10 and 12-15, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

Applicants amended claims 1, 5-10 and 12-15 are drawn to compounds 8 to 50

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nucleotides in length targeted to nucleobases 501 through 926 of a nucleotide encoding Sonic Hedgehog (SHH) of SEQ ID NO: 3.

A thorough review of the specification and particularly of Table 1, which lists the oligos targeting SEQ ID NO: 3, indicates that applicants had not, previous to this amendment, disclosed targeting the entirety of the newly recited target region of 501 through 926 of a nucleotide encoding Sonic Hedgehog (SHH) of SEQ ID NO: 3. Accordingly, the instant specification is not considered to support claims directed to the region of 501 through 926, and is thus considered to introduce new matter. For example, applicants teach targeting using 20mer oligos nucleotides 721 through 741, and to 790 through 810 of the instant SEQ ID NO: 3, but do not teach targeting nucleotides 742-789 as now claimed. If applicant disagrees, applicant is requested to indicate with particularity by page and line number where such support exists for the targeting of the entirety of the region now claimed.

#### Prior Art

Rejections under 35 U.S.C. § 112 first paragraph notwithstanding, claims 1, 5-10 and 12-15 are considered to be free of the prior art searched.

#### Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JDS

JD Schultz Patent Examiner,

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